

Press Release For Immediate Release

# Glenmark announces Strategic Development and Global Licensing Agreement with Particle Sciences, Inc., a Lubrizol Company, for generic ABRAXANE®

- Glenmark obtains global exclusive Commercial Marketing and Distribution rights for the product
- Development initiated for the US market with an Abbreviated New Drug Application (ANDA) expected to be filed in FY19; subsequently the product will be filed in other key markets
- Particle Sciences to receive milestone payments on various stages of the product's development from Glenmark, including royalties on sales

**Mumbai, India; September 19, 2016:** Glenmark Pharmaceuticals, Inc., USA (Glenmark) today announced that it has entered into a strategic Development, License and Commercialization Agreement with Particle Sciences, Inc. to develop and market a generic version of Celgene's ABRAXANE® product – paclitaxel protein (albumin)-bound particles for injectable suspension.

As per the terms of the agreement, Glenmark has obtained Global Exclusive Marketing and Distribution rights of the product upon commercialization. Particle Sciences will develop this product exclusively for Glenmark, and shall receive certain milestone payments during various stages of the product's development from Glenmark, including royalties on sales. Development of the product has been initiated for the USA market and Glenmark intends to file the ANDA in FY19. The product will be subsequently filed in other key markets across the globe.

"The partnership is a significant development in Glenmark's complex generics strategy and we are pleased to collaborate with Particle Sciences given their strong technical capabilities and understanding of particulate injection products. This is a challenging product to develop and we expect it to remain a limited competition opportunity." said Robert Matsuk, President – North America and Global API, Glenmark Pharmaceuticals Limited.

ABRAXANE® marketed globally by Celgene has reported sales of USD 967 million world-wide and USD 654 million in the USA in the calendar year 2015. As per IMS MAT December 2015, ABRAXANE® has registered sales of USD 990 million world-wide and USD 669 million in the USA.

ABRAXANE® is paclitaxel protein (albumin)-bound particles for injectable suspension indicated for the treatment of:

- Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated
- Locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment in combination
  with carboplatin, in patients who are not candidates for curative surgery or radiation therapy
- Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine

## Glenmark Pharmaceuticals Ltd.



#### **About Glenmark Pharmaceuticals Limited**

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2016). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain]. The company has a significant presence in the branded generics markets across emerging economies including India. GPL along with its subsidiaries operate 17 manufacturing facilities across four countries and has five R&D centers. The Generics business of Glenmark services the requirements of the US and Western European markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India.

## **About Particle Sciences**

Particle Sciences, part of Lubrizol LifeSciences, is an integrated provider of drug development services. Particle Sciences focuses on BCS II/III/IV molecules, biologics and highly potent compounds through a variety of technologies including emulsions, gels, micro and nano-particulates, drug/device combination products, solid solutions and others. Particle Sciences is FDA registered and DEA licensed. Through a full range of formulation, analytic and manufacturing services, Particle Sciences provides pharmaceutical companies with a complete and seamless development solution that minimizes the time and risk between discovery and the clinic. The company was founded in 1991 and is headquartered in Bethlehem, Pennsylvania. Visit <a href="www.particlesciences.com">www.particlesciences.com</a>, or contact Particle Sciences at (610) 861- 4701 for information.

#### **About The Lubrizol Corporation**

The Lubrizol Corporation, a Berkshire Hathaway company, is a technology-driven global company that combines complex, specialty chemicals to optimize the quality, performance and value of customers' products while reducing their environmental impact. It produces and supplies technologies to customers in the global transportation, industrial and consumer markets. These technologies include lubricant additives for engine oils, driveline and other transportation-related fluids, industrial lubricants, as well as additives for gasoline and diesel fuel. In addition, Lubrizol makes ingredients and additives for home care and personal care products and specialty materials encompassing polymer and coatings technologies, along with polymer-based pharmaceutical and medical device solutions. Our products for the oilfield market include technologies for exploration, production and transportation. With headquarters in Wickliffe, Ohio, Lubrizol owns and operates manufacturing facilities in 17 countries, as well as sales and technical offices around the world. Founded in 1928, Lubrizol has approximately 9,000 employees worldwide. Revenues for 2015 were \$7 billion. For more information, visit Lubrizol.com.

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